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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,697	08/05/2003	Pablo Umana	1975.0010005/TJS/AWL	5455

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,697	UMANA ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-93,95-100,102-123,125-132,158-160 and 163-166* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-88,90,93,95-97,99,102,104-113,120-123,125-129,131,132,158-160 and 163-166* is/are rejected.

7)☒ Claim(s) *89,91,92,98,100,103,114-119 and 130* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/07 has been entered.

The Terminal Disclaimers filed 10/22/07 with regard to US 6,602,684 and 11/199,232 are acceptable and have been entered.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 86-88, 102, 110-112, 120, 121, 123, 159, 160, 163-165 and 166 are rejected under 35 U.S.C. 102(a) as being anticipated by Patel et al.

Applicants claim a method for producing a recombinant antibody having increased Fc mediated cellular cytotoxicity or having increased Fc receptor binding affinity, comprising: (a) providing a mammalian host cell that expresses a recombinant

antibody comprising an IgG Fc region containing N-linked oligosaccharides; (b) glycoengineering said host cell so that said host cell has an altered level of activity of at least one glycoprotein-modifying glycosyltransferase; (c) culturing said glycoengineered host cell under conditions which permit the production of said recombinant antibody; and (d) isolating said recombinant antibody; wherein said recombinant antibody has increased Fc-mediated cellular cytotoxicity compared to the corresponding antibody produced by the same host cell that has not been glycoengineered.

Patel et al. (WO 97/30087, published 8/21/1997, cited by applicants, see whole document, particularly pp. 2-4, 6-9, etc.) teaches methods of producing recombinant antibodies having increased Fc mediated ADCC comprising providing a mammalian host cell that expresses a recombinant antibody (can be a complete IgG comprising an Fc region with a CH2 domain and containing N-linked oligosaccharides), transforming said cell with vectors encoding and expressing exogenous glycoprotein-modifying glycosyltransferase enzymes (galactosyltransferases or sialyltransferases), culturing the cells so as to express the antibody with increased ADCC compared to the corresponding antibody produced by the same host cell that has not been glycoengineered. With regard to increased Fc receptor binding affinity, it must be considered that altering the glycosylation patterns by the method of Patel et al. would produce enhanced ADCC by increased Fc receptor binding affinity as this is a property of antibodies with increased ADCC. The host cell can be a CHO cell (Patel et al. references Gramer et al. on p. 6 for cell lines usable in the context of the invention, said reference teaches CHO cells). The antibody produced can be a monoclonal or chimeric

or humanized antibody and the antibody can be a therapeutic antibody directed against antigens expressed by a cancer (i.e. colorectal cancer) cell. Patel et al. therefore teaches the claimed invention.

Obviousness Type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 86-88, 90, 93, 99, 102, 104, 106-113, 120-123, 125-129, 131-132, 158-160 and 163-166 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 228-260 of copending Application No. 10/761,435. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for producing a recombinant antibody having increased effector function including

increased ADCC activity and Fc receptor binding activity. The instant claims are generic in that they recite glycoengineering host cells to have an altered level of any glycoprotein modifying glycosyltransferase (also both sets of claims recite expression of α-mannosidase II in host cells).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 86-88, 90, 93, 97, 99, 102, 104, 106-113, 120-123, 125-129, 131-132, 158-160 and 163-166 are directed to an invention not patentably distinct from claims 228-260 of commonly assigned 10/761,435. Specifically, the claims are not patentably distinct for reasons outlined in the above obviousness type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/761,435, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 95-96 and 105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants recite in claims 95-96 and 105 language reading on "at least one glycoprotein-modifying glycosyl transferase is" followed by two different glycosyl transferases connected with the word "and". It is unclear if applicants are claiming a single protein molecule comprising both enzyme activities or a fusion protein between the two enzymes or are claiming two separate enzyme molecules.

Miscellaneous

The instant claims recite "glycoengineering" host cells so as to alter the level of activity of at least one glycoprotein-modifying glycosyltransferase; however, the application, as filed does not disclose the term "glycoengineering". The specification does recite the term "glycosylation engineering" and it is assumed that the two terms

are synonymous. However, in the interest of consistency, it is suggested that applicants amend the claims to delete "glycoengineering" and substitute the term "glycosylation engineering". Alternatively, if applicants retain the term "glycoengineering", applicants are requested to indicate on the record that the terms "glycoengineering" and "glycosylation engineering" have **precisely** the same definition.

No Claims are allowed.

Claims 89, 91-92, 98, 100, 103, 114-119 and 130 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
January 3, 2008

DAVID GUZO
PRIMARY EXAMINER